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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,315	09/24/2001	Robert W. Wannemacher	12694/P66821US2 (RIID99-2	6514

53502 7590 10/06/2006

OFFICE OF THE STAFF JUDGE ADVOCATE (SKS)
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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,315	WANNEMACHER ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 47-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *25 and 47-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/523,271; which claims the benefit of the filing date of provisional application 60/124,283.

Claims 1-24 and 26-46 have been canceled.

New claims 47-55 have been added.

Claims 25 and 47-55 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment, only the following ground of rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 25 stands rejected under 35 U.S.C. 102(b) as being anticipated by Thorpe et al (Eur. J. Biochem. [1985] 147:197-206; AV on form PTO-1449).

It was previously stated: Applicant's claimed method consists of a single step, which is the administration an amount of chemically deglycosylated ricin A chain, wherein the ricin B-chain has been removed. The recitation in the claim of inducing a particular titer of anti-ricin antibodies is merely a characterization of the result of practicing the method and does not limit the method itself.

Thorpe teaches the deglycosylation of ricin A chain with sodium metaperiiodate and cyanoborohydride at a pH of 3.5 at 4°C (page 198, second column in particular). Thorpe teaches that the level of deglycosylation was dependent upon the incubation time and a maximum of 13 out of the total 18 mannose residues were destroyed (Abstract in particular). Thorpe teaches in Figures 2 and 3 that after 60 minutes of $IO_4^-/CNBH_3$ treatment (specifically recited in instant claim 18) about 50% of the mannose is destroyed and Figure 2 further shows that most fucose is destroyed. Thorpe further teaches that the 60-minute composition was administered to animals (Table 2 in particular) and that "the duration of treatment of ricin with $IO_4^-/CNBH_3$ that gives maximal avoidance of reticuloendothelial recognition with least reduction in cytotoxic activity is 60 min under the conditions used in this study" (page 205, last paragraph of column 1 in particular). Thorpe teaches the administration of 20 μg/kg to rat subjects (Table 3 in particular). Thorpe teaches that ricin immunotoxins prepared in this manner to be administered to subjects can be just the A chain of the ricin molecule (page 205, last paragraph of column 1 in particular; emphasis added to show difference from previous ground of rejection). While Thorpe is silent regarding the production of ricin-reactive antibodies in the treated subject, Thorpe teaches administration of ricin A chain that has been incompletely deglycosylated in the same manner as that disclosed in the instant specification (page 7, line 17 to page 8, line 5 for example) within the claimed range of administration. Accordingly, the production of antibodies to ricin is inherent to the method of incompletely deglycosylated ricin A chain administration taught by Thorpe. Furthermore, given the indefiniteness

concerning titer in claim 17 and as addressed in paragraph 2 *supra*, the recited titer would have inherently been achieved by the artisan using the method of Thorpe based solely upon manipulation of the ELISA conditions used.

The prior art teaching anticipates the claimed invention."

Applicant's arguments filed July 12, 2006 have been fully considered but they are not persuasive. Applicant argues that Thorpe does not anticipate the claimed invention because Thorpe does not provide the immunochemistry of a ricin A chain with the B chain removed. This is not convincing because Thorpe clearly teaches that the B chain can be separated from the A chain, and that the A chain can be administered without the B chain.

The following new grounds of rejection have been necessitated by Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 47-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 47 broadly recites "protecting a subject from ricin intoxication by inhalation." However, the only type of "protection" that is disclosed in the specification or claims as originally filed is "immunization" of the subject. The instant specification does not disclose any other type of "protection." Applicant is reminded that obviousness is not the standard for the addition new limitations to the disclosure as filed. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). In the instant case, a limitation for "protection" may be obvious over immunization but is not supported by the specification or claims as originally filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is ambiguous and unclear in reciting both "vaccine" and "immunogenic composition" in the Markush group. According to base claim 47, the composition must "protect" the subject. Accordingly, there is no difference in scope between the two terms and the terms therefore constitute a double inclusion in the Markush Group.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 25 and 47-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorpe et al (Eur. J. Biochem. [1985] 147:197-206; AV on form PTO-1449: of record) in view of Yan et al (Vaccine [1996] 14(11):10312-1038; U on form PTO-892 : newly cited).

Thorpe has been discussed supra.

Thorpe does not teach protecting a subject from ricin intoxication.

Yan teaches that intranasal administration of ricin toxoid vaccine provides long-lasting protection from ricin intoxication by inhalation (Abstract in particular). Yan also teaches that parenteral

administration of ricin toxoid stimulated anti-ricin antibody production and protected against ricin intoxication (page 1032, first column and page 1037, fist column in particular).

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to deglycosylate ricin A chain according to the method of Thorpe and use it parenterally or intranasally to protect a subject against ricin intoxication. One would have been motivated to combine the teachings with a reasonable expectation of success by the teachings of Thorpe that deglycosylation of ricin A chain gives maximal avoidance of reticuloendothelial recognition and the teachings of Yan that even a single dose of a ricin toxoid vaccine stimulate systemic anti-ricin IgG antibodies and can protect a subject from ricin intoxication for at least 1 year.

Conclusion

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
September 26, 2006

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